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10/069,605	02/26/2002	Keith M Skubitz	09531-203US1	3442

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EXAMINER	
EMCH, GREGORY S	
ART UNIT	PAPER NUMBER
1649	

NOTIFICATION DATE	DELIVERY MODE
12/18/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No.	Applicant(s)	
	10/069,605	SKUBITZ ET AL.	
	Examiner	Art Unit	
	Gregory S. Emch	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-10,19,21,22,27 and 29-31* is/are pending in the application.

4a) Of the above claim(s) *19,21 and 22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-10,27 and 29-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Claims 1 and 27 have been amended and claims 2, 20 and 28 have been canceled as requested in the amendment filed on 15 October 2008. Following the amendment, claims 1, 5-10, 19, 21, 22, 27 and 29-31 are pending in the instant application.

Claims 19, 21 and 22 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1, 5-10, 27 and 29-31 are under examination in the instant office action.

Request for Rejoinder

In the reply filed on 15 October 2008, Applicants assert that the amendments herein result in a common technical feature between the pending claims and the withdrawn, non-elected claims 19, 21 and 22. Applicants assert that for example, independent claim 19 corresponds essentially to a method of using the isolated peptide of claim 1. Therefore, Applicants request that claims 19, 21 and 22 be rejoined with the elected claims under PCT Rule 13 and MPEP §821.04.

Applicants' arguments have been fully considered and are not found persuasive. Applicants' attention is directed to MPEP §821.04, which states, "The propriety of a restriction requirement should be reconsidered when all the claims directed to the

elected invention are in condition for allowance, and the nonelected invention(s) should be considered for rejoinder." As set forth below, all of the claims directed to the elected invention are not in condition for allowance. Hence, the nonelected invention will not be considered for rejoinder in the instant office action.

Withdrawn Objection/Rejections

The objection to claims 1 and 27 for the recitation of "represented by SEQ ID NO: 14" is withdrawn in response to the amendment of said claims.

The objection to claim 2 for the recitation of "represented by SEQ ID NO: 14" is withdrawn as moot in response to the cancellation of said claim.

The written description and scope of enablement rejections of claims 2 and 28 under 35 U.S.C. 112, first paragraph are withdrawn as moot in response to the cancellation of said claims.

The rejection of claim 28 under 35 U.S.C. 102(b) as being anticipated by Watt et al. is withdrawn as moot in response to the cancellation of said claim.

The rejection of claim 28 under 35 U.S.C. 102(b) as being anticipated by Barnett et al. is withdrawn as moot in response to the cancellation of said claim.

Remaining issues are set forth below.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 1, 5-10, 27 and 29-31 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained for reasons of record and as set forth below. The claim contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

In the reply filed on 15 October 2008, Applicants assert that they have amended claims 1 and 27 to remove "biologically active fragments." Thus, Applicants request that both rejections under 35 U.S.C. 112, first paragraph be withdrawn.

Because the claims are drawn to isolated peptides comprising "an amino acid sequence as shown in SEQ ID NO: 14" (and a method of use thereof), these are genus claims. Although Applicants have amended the claims to delete the recitation of "biologically active fragments," the recitation of "an amino acid sequence as shown in SEQ ID NO: 14" still reads on small fragments of SEQ ID NO: 14, e.g. even fragments with as little as two amino acids of SEQ ID NO: 14. To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only structural factor present in the claims is a partial structure in the form of a recitation of "an amino acid sequence as shown in

SEQ ID NO: 14" which can encompass as little as two amino acids of SEQ ID NO: 14. There is not even identification of any particular portion of the claimed structure that must be conserved. Thus, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

As set forth previously, with the exception of the complete peptide of SEQ ID NO: 14, the skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Thus, only isolated peptides comprising the full-length, unaltered amino acid sequence of SEQ ID NO: 14, but not the full breadth of the claims meets the written description provision of 35 U.S.C. §112, first paragraph. Applicants are reminded that

Vas-Cath makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115). It is noted that if the claims were amended to recite "the" amino acid sequence, rather than "an" amino acid sequence, such would be remedial.

The scope of enablement rejection of claims 1, 5-10, 27 and 29-31 under 35 U.S.C. 112, first paragraph, is maintained for reasons of record and as set forth below. This is because the specification, while being enabling for an isolated peptide comprising "the" amino acid sequence of SEQ ID NO: 14 and a method comprising the use of said peptide, does not reasonably provide enablement for the full scope of an isolated peptide comprising "an" amino acid sequence as shown in SEQ ID NO: 14 and a method of use thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and, (8) the breadth of the claims. *In re Wands*, 8 USPQ2d, 1400 (CAFC 1988).

As set forth above, Applicants assert that they have amended claims 1 and 27 to remove "biologically active fragments." Thus, Applicants request that both rejections

under 35 U.S.C. 112, first paragraph be withdrawn.

Applicants' arguments have been fully considered and are not found persuasive. The instant claims require the use of a broad genus of peptides and as stated above, Applicants have not described all of the common features of the genus such that the skilled artisan could identify individual members. The potential amino acid sequences encompassed by the claim have particular structures, the predictability of which is complex and outside the realm of routine experimentation. Since detailed information regarding the structural requirements of the multitude of potential amino acid sequences encompassed by the claims are lacking, and given the lack of working examples reciting any and all of the sequences encompassed by the claims, it is unpredictable as to which variations, if any, meet the limitations of the claims. The art supports the unpredictability of the claimed invention. As stated previously, relevant art regarding biliary glycoprotein (BGP; i.e., an amino acid molecule comprising the amino acid sequence of SEQ ID NO: 14) and BGP splice variants (including those comprising fragments of the amino acid sequence of SEQ ID NO: 14) often have divergent functions. Specifically, Barnett et al (cited previously) teaches that BGP isoforms probably have diverse *in vivo* functions and that fusions comprising the extracellular domain of BGPa and an Fc immunoglobulin fragment and a BGPb-Fc have different functions (p.1280, ¶ 2 and 3). Thus, the predictability of amino acid sequences that would function as claimed is complex and outside the realm of routine experimentation.

The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without such guidance, the

changes which can be made and still maintain activity/utility is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See Ex parte Forman, 230 USPQ 546 (Bd. Pat. App. & Int. 1986).

The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. Due to the large quantity of experimentation necessary to practice the claimed invention, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the claimed methods, and the breadth of the claims which encompass peptides with as little as two amino acids of SEQ ID NO: 14, undue experimentation would be required of the skilled artisan to practice the claimed invention in its full scope. It is again noted that if the claims were amended to recite "the" amino acid sequence, rather than "an" amino acid sequence, such would be remedial.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1, 5-10, 27 and 29-31 under 35 U.S.C. 102(b) as being anticipated by Watt et al. (item AFFFF on IDS dated 10 December 2004) is maintained for reasons of record and as set forth below.

In the reply filed on 15 October 2008, Applicants assert that they have amended independent claims 1 and 27 to specifically refer to SEQ ID NO: 14. Thus, Applicants request that the instant rejection be withdrawn.

Applicants' arguments have been fully considered and are not found persuasive. As set forth above, because of the recitation of "an amino acid sequence as shown SEQ ID NO: 14," the claims still encompass fragments of SEQ ID NO: 14. Therefore, contrary to Applicants' assertion, independent claims 1 and 27 do not only specifically refer to SEQ ID NO: 14. Regardless as stated previously, the Watt et al. reference teaches biliary glycoprotein (BGP), which comprises an amino acid sequence that is 100% identical with the amino acid sequence of SEQ ID NO: 14 and splice variants, which comprise fragments of the amino acid sequence of SEQ ID NO: 14. Thus, the rejection is properly maintained.

The rejection of claims 1, 5-7, 27 and 30 under 35 U.S.C. 102(b) as being anticipated by Barnett et al (cited previously) is maintained for reasons of record and as set forth below.

In the reply filed on 15 October 2008, Applicants assert that they have amended independent claims 1 and 27 to specifically refer to SEQ ID NO: 14. Thus, Applicants request that the instant rejection be withdrawn.

As set forth above, because of the recitation of "an amino acid sequence as shown SEQ ID NO: 14," the claims still encompass fragments of SEQ ID NO: 14. Therefore, contrary to Applicants' assertion, independent claims 1 and 27 do not only specifically refer to SEQ ID NO: 14. Regardless as stated previously, the Barnett et al. reference teaches biliary glycoprotein (BGP) that comprises an extracellular domain (II a), which comprises an amino acid sequence which is 100% identical to the amino acid sequence of SEQ ID NO: 14 (see Figure 5B, p.1279). Thus, the rejection is properly maintained.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory S. Emch whose telephone number is (571) 272-8149. The examiner can normally be reached 9:00 am - 5:30 pm EST (M-F).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached at (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/G.E./

Gregory S. Emch, Ph.D.
Patent Examiner
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11 December 2008

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